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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,900	06/23/2006	Francois Schutze	032013-120	5877

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CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON, DC 20044-4300

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,900	SCHUTZE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16, 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed May 26, 2009 is acknowledged. Claims 12-16 and 21 remain under consideration. A Response filed July 27, 2009 to the Interview Summary mailed June 26, 2009, in which Applicants basically concur with the points made in the Interview Summary, is further acknowledged.

Those rejections set forth in previous Office Actions that are not herein reiterated are withdrawn. The following objection and rejections constitute the only objection and rejections that are presently applied to the instant claims.

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: "judgement" on page 7, line 11, and "disapearance" on page 12, line 9. Adherence to standard American English with respect to the words "favorable" and "esophagus" is requested.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 21 recites the limitation "a salt of sodium, potassium, magnesium or calcium." There is insufficient antecedent basis for this limitation in claim 12 from which claim 21 depends.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-16 and 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of allowed, copending Application No. 10/561844 in the last Office Action. This application has now matured to U.S. Patent 7,402,593.

Claims 12-16 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 7,402,593. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass a medicament comprising enantiomers of tenatoprazole for use in the treatment of gastroesophageal reflux disease.

Claims 12-16 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 9 and 12-14 of U.S. Patent No. 7,034,038. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the co-pending claims are drawn to compositions comprising enantiomers of tenatoprazole to treat gastroesophageal reflux disease and Barrett's esophagus.

Claims 12-16 and 21 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-20 of copending Application No. 11/344212 in the last Office Action. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass a medicament comprising enantiomers of tenatoprazole for use in the treatment of Barrett's esophagus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants choose to hold these obviousness-type double patenting rejections in abeyance.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. The claims are directed to treating Barrett's

esophagus comprising administering tenatoprazole. Further, according to the instant specification, methods of prevention are encompassed in the present claims. See page 533, to page 6, line 2. The present specification does not reasonably provide enablement for said methods within the full scope of the claims.

To be enabling, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir., 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547, the court recited eight factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. with expertise in the area of gastroenterology. However, that factor is outweighed by the unpredictable nature of nocturnal heartburn and Barrett's esophagus, as indicated by The Merck Manual.

According to The Merck Manual, which is cited for evidentiary purposes only, the treatment of Barrett's esophagus subsequent to the administration of tenatoprazole would not have been predictable. See the discussion under **Esophageal Cancer**, page 321. As such, one skilled in the medical arts would not have readily accepted an assertion that the administration of tenatoprazole predictably results in an efficacious treatment for Barrett's esophagus. Barrett's esophagus is a more complex pathology than gastroesophageal reflux disease.

In cases involving unpredictable factors, such as the instant claims drawn to physiological activity, the scope of enablement varies inversely with the degree of unpredictability of the factors involved. One skilled in the chemical or biological arts cannot always reasonably predict how different chemical compounds might behave under varying circumstances. See *Ex parte Sudilovsky* 21 USPQ2d 1701.

The amount of direction or guidance provided and the presence or absence of working examples

A review of the specification fails to provide clear support for the treatment of Barrett's esophagus. There are no working examples in the specification to support such a method.

Tables 2-5, pages 9-14, in the specification demonstrate efficacy in treating atypical symptoms of gastroesophageal reflux, such as pharyngitis, dysphonia, nocturnal cough, and disappearance of erosion. However, the characteristics of Barrett's present a more clinically serious condition because a columnar, glandular, stomach-like mucosa replaces the normal stratified squamous epithelium of the distal esophagus during the healing phase of acute esophagitis. Most adenocarcinomas of the distal esophagus arise in Barrett's esophagus.

The quantity of experimentation necessary

Absent reasonable *a priori* expectations of success, one skilled in the gastroenterology art would have had to test laboratory models of Barrett's,

administering tenatoprazole in various dosages and dosing regimens, in order to demonstrate an effect.

Due to the known unpredictability of the art, and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that administering tenatoprazole would result in a treatment modality for Barrett's esophagus. The instant claims do not comply with the enablement requirements of 35 U.S.C. 112, first paragraph, since to practice the claimed invention would require a person of ordinary skill in the art to engage in undue experimentation with no assurance of success.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al., US 2006/0024238.

Barth teaches the administration of a proton pump inhibitor, such as tenatoprazole, or a pharmaceutically acceptable salt thereof, in the treatment of atypical and esophageal symptoms of gastroesophageal reflux disease (GERD). Barth's teaching also encompasses treating Barrett's esophagus. See paragraph [0009], page 2, paragraph [0044] page 5, and claims 9, 12, 14 and 18, pages 13-14. Tenatoprazole is specifically included in Barth's teaching in claim 18. Dosages, as required by instant

claims 15 and 16, are taught to be preferably about 10-30 mg per day, in paragraph [0091], page 9. As required by instant claim 14, injectable preparations are disclosed in paragraph [0096], page 9. Medicaments comprising proton pump inhibitors for oral administration are disclosed in paragraph [0097] on page 10.

Applicants argue tenatoprazole is mentioned for the first time in the chain of Barth applications on May 16, 2003. Applicants' priority date, based on French Application No. 0213113, is October 21, 2002. Applicants urge there is no specific disclosure in the provisional applications of Barth reciting tenatoprazole, and the prior art does not recognize advantages of using tenatoprazole.

Provisional application 60/404,154, filed August 19, 2002, states on page 15 of the specification, that any proton pump inhibitor is encompassed in the teaching. See lines 23-24, and page 7, lines 22-23, in Provisional application 60/380,855. It is stated on page 3, line 12, of the '154 provisional application that any gastrointestinal disorder is encompassed in the disclosure. Gastroesophageal reflux disease, as well as Barrett's esophagus, is recited.

A review of the specification fails to provide clear support for the treatment of Barrett's esophagus, as discussed *supra*.

Further, although a treatment of nocturnal heartburn is shown in the Tables, there is no comparison to other proton pump inhibitors. One skilled in the art would have expected an improvement in nocturnal heartburn subsequent to the administration of any proton pump inhibitor.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 5, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614